U.S. Senator Judd Gregg, Chairman

Senate Committee on Health, Education, Labor and Pensions

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GREGG-SCHUMER AMENDMENT PASSES FULL SENATE LOWER COST PRESCRIPTION DRUGS NOW PART OF MEDICARE REFORM BILL

WASHINGTON- The U.S. Senate today voted to include an amendment, introduced by Senator Judd Gregg (R-NH), Chairman of the Senate Health, Education, Labor and Pensions Committee and Senator Charles Schumer (D-NY) to make more affordable prescription drugs available to more people more quickly, in the Senate Medicare bill.

"This amendment is a victory not just for seniors, but for every person in American who has ever used a prescription drug. We have crafted legislation that eliminates the delaying tactics some name brand and generic drug companies have used in the past to keep lower cost prescription drugs off the market and away from consumers. At the same time, we protect innovation and preserve the incentive for companies to invest in research and development," said Senator Judd Gregg.

"For people paying top dollar for prescription drugs, relief is finally in sight. We cleared a major hurdle today in the effort to get rid of an obsolete law that keeps affordable drugs from being sold in pharmacies," Schumer said. "This legislation uses a market-based approach that doesn't cost the government a penny and gives the drug industry a desperately needed dose of competition. It's all about easing the burden on everyday people who are forced to rely on higher-priced name brand drugs because no cheaper alternative is available."

Summary of the Gregg-Schumer Greater Access to Affordable Pharmaceuticals Amendment:

Current US drug patent laws (known as Hatch-Waxman) were designed to strike a balance between rewarding blockbuster drug companies for their research and development while ensuring that less expensive generic drugs are available to consumers. But in the years since these laws were enacted, the namebrand industry has stifled low-cost competition with a host of tactics - including filing frivolous patents with the FDA on the color of a pill bottle and paying generic manufacturers not to sell their drugs. In so doing, these tactics allow the namebrand companies to keep charging exorbitant prices and delay the arrival of lower-cost alternatives.

These tactics have caused drug prices to soar and forced the gap between the cost of brand name drugs and their generic alternatives to skyrocket in the last decade. In 1990, the average cost per prescription for brand-name medications was $27.16, while the average cost for generic drugs was $10.29. By 2000, the average cost per prescription reached $65.29, while the generic increased to only $19.33. Last summer, the Senate passed legislation sponsored by Schumer and McCain that significantly overhauled Hatch-Waxman. For the individual, that legislation would have meant hundreds of dollars in savings on drug costs per year.

The Gregg-Schumer proposal would achieve comparable savings to the original Schumer-McCain measure but uses a different approach to modify the patent laws. In so doing, it addresses a number of the criticisms made against Schumer-McCain. The key elements of the Gregg-Schumer proposal are as follows:

1) **One 30 Month Stay** - The name-brand company would get a single 30 month stay. The stay would be triggered if a name-brand company sues a generic application for infringing on any patent on a blockbuster drug that is filed before a generic application is submitted to the FDA.

Once a generic application is filed, the name-brand company has 45 days to challenge the generic application in court. If the name brand does not challenge the generic company's application within 45 days, the generic can seek a declaratory judgement indicating that it does not violate the name-brand drug's patents.

The single 30-month stay would run concurrent to the FDA's consideration of the generic company's application. As such, the 30-month stay would not be likely to cause significant delay in the generic's introduction to the marketplace. (It usually takes the FDA 18 to 25 months to approve a generic drug.) In contrast, the FDA's proposed rule would allow the stay to be triggered up to the eve of the generic drug coming to market.

2) **Enforcement** - The Gregg-Schumer plan does not specify which patents can be listed in the FDA's Orange Book. To ensure that the name-brand companies do not use frivolous patents to keep generic drugs off the market, the proposal would create a new enforcement mechanism.

Gregg-Schumer would allow generic companies to file counter-claims if a name-brand company sues them for violating a patent. For example, if a name brand files a frivolous patent and sues a generic applicant for violating that patent in order to trigger the 30-month stay, the generic company can counter-sue the name brand and argue that the patent should never have been listed in the Orange Book in the first place.

3) **180 Day Exclusivity** - Currently, the first generic drug company who is able to come to market gets 180 days of exclusivity. Gregg-Schumer sets up "forfeiture provisions" similar to those in earlier generic drug legislation which prevent the generic companies from abusing this incentive.

Under the bill, a generic drug company would forfeit its rights to this exclusivity if it was found to have made an anti-competitive deal with a brand company or otherwise fails to come to market in a timely manner. If one of the forfeiture provisions outlined in the bill occurs, the exclusivity would be forfeited and the marketplace would open up to any generic company ready to come to market.

4) **Bioequivalence** - Under the current statute, the primary method by which the FDA determines whether a generic is equivalent to a brand drug ("bioequivalence") is by measuring the rate and absorption of the drug into the bloodstream. For certain drugs which are not absorbed into the bloodstream, such as topicals and inhalers, the FDA uses different tests to determine bioequivalence, which are defined in their regulations. Brand companies have challenged FDA's use of these regulations, which has led to delay in the approval of generic versions of these drugs. Gregg-Schumer would clarify that the FDA does have the authority to establish separate tests for determining the bioequivalence of drugs which are not absorbed into the bloodstream - as long as those tests are scientifically valid and meet rigorous standards.

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